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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
FORD, VANESSA L	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/708,352
Filing Date: November 08, 2000
Appellant(s): LEONARD ET AL.

LEONARD ET AL.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 7, 2008 appealing from the Office action mailed May 25, 2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

An amendment after-final was filed October 24, 2005 but was not entered.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the issues in the brief is correct. The rejection of claims 1, 4, 5, 7, 29, 30 and 56 as anticipated by Thorns et al *(Res. Vet Sci. 29:328-332)* has been withdrawn.

(7) Claims Appendix

Appellant's copy of the appealed claims contained in the appendix is correct.

(8) Evidence Relied Upon

Boothby *(Immunologic Responses to Mycoplasma bovis, University Microfilm International (Dissertation))* 1-72, 1982.

Thorns et al, *(Res. Vet Sci. 29:328-332).*

Poumarat et al. *(Vet. Microbiol., 1994, 40:305-321).*

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

I. The rejection of claims 1, 3, 5-6, 29-30, 40-44 and 52-55 under 35 U.S.C. 102(b) as anticipated by Boothby, *(Immunologic Responses to Mycoplasma bovis, University Microfilm International (Dissertation) 1-172, 1982).*

Independent claim 1 is drawn to a vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one inactivated or attenuated *Mycoplasma bovis* biotype, an adjuvant and a pharmaceutically acceptable excipient and wherein the adjuvant does not include saponin and the clinical disease includes respiratory pneumonia.

Independent claim 5 is drawn to a vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one inactivated or attenuated *Mycoplasma bovis* biotype, an adjuvant and a

pharmaceutically acceptable excipient wherein at least two of the inactivated or attenuated *Mycoplasma bovis* biotypes is selected from the groups consisting of biotype A, biotype B, biotype C and wherein the adjuvant does not include saponin.

Independent claim 29 is drawn to a vaccine which is protective against *Mycoplasma bovis* mastitis in a bovine species following systemic administration.

Independent claim 52 is drawn to a whole cell vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one inactivated and attenuated *Mycoplasma bovis* biotype and an adjuvant selected from the group consisting of an aluminum hydroxide-oil emulsion, a mineral, vegetable or fish oil-water emulsion, a water-in-oil emulsion, *E. coli* J5, dextran sulfate, iron oxide, sodium alginate, Bacto-Adjuvant, a synthetic polymer, Carbopol, a poly-amino acid, a co-polymer of amino acids, carrageenan, REGRESSIN®, N,N-dioctadecyl-N'-N'-bis(2-hydroxethyl)propanediamine, a long chain polydispersed β(1,4) linked mannan polymer interspersed with O-acetylated groups, deproteined cell wall extracts from a non-pathogenic stain of Mycobacterium, mannite monooleate and paraffin oil.

Boothby teaches a vaccine composition comprising killed *Mycoplasma bovis* and phosphate buffered saline (PBS) used for systemic immunization of calves (page 130). Boothby teaches that the vaccine preparations used contained 5.00 mg/ml of antigen for immunization (page 131) which meets the claim limitation " wherein the amount of each inactivated biotype is at least 10^8 *M. bovis* cells". Boothby teaches that cows vaccinated with *M. bovis* antigen in PBS elicited a moderate indirect hemagglutinations (IHA) response to systematic vaccination, an IgG ELISA response and an ELISA IgA

response (page 133). Boothby et al teach that preparations for systemic immunization included Freund's Incomplete Adjuvant (page 131). Boothby et al teach that the highest respiratory IgA reactivity was found in the nasal secretions of the group which was vaccinated with *M. bovis* in PBS (page 134). Boothby et al teach that there was no sign of respiratory illness in any calves used in the study (page 136). Therefore, the vaccines were protective against respiratory infection caused by *M. bovis*.

Since the Office does not have the facilities for examining and comparing applicant's vaccine with vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the products of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

II. Claims 1, 3-12 and 29-56 under 35 U.S.C. 103(a) are unpatentable over Boothby *(Immunologic Responses to Mycoplasma bovis, University Microfilm International (Dissertation) 1-172, 1982)* in view of Poumarat et al *(Veterinary Microbiology, 40, 1994, 305-321)* further in view of Thorns et al *(Res. Vet. Sci., 1980, 29(3), 328-332)*.

Independent claim 1 is drawn to a vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one inactivated or attenuated *Mycoplasma bovis* biotype, an adjuvant and a

pharmaceutically acceptable excipient and wherein the adjuvant does not include saponin and the clinical disease includes respiratory pneumonia.

Independent claim 5 is drawn to a vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one inactivated or attenuated *Mycoplasma bovis* biotype, an adjuvant and a pharmaceutically acceptable excipient wherein at least two of the inactivated or attenuated *Mycoplasma bovis* biotypes is selected from the groups consisting of biotype A, biotype B, biotype C and wherein the adjuvant does not include saponin.

Independent claim 8 is drawn to a vaccine which protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least two inactivated or attenuated *Mycoplasma bovis* biotypes and a pharmaceutically acceptable excipient.

Independent claim 29 is drawn to a vaccine which is protective against *Mycoplasma bovis* mastitis in a bovine species following systemic administration.

Independent claim 52 is drawn to a whole cell vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one inactivated and attenuated *Mycoplasma bovis* biotype and an adjuvant selected from the group consisting of an aluminum hydroxide-oil emulsion, a mineral, vegetable or fish oil-water emulsion, a water-in-oil emulsion, *E. coli* J5, dextran sulfate, iron oxide, sodium alginate, Bacto-Adjuvant, a synthetic polymer, Carbopol, a poly-amino acid, a co-polymer of amino acids, carrageenan, REGRESSIN®, N,N-dioctadecyl-N'-N'-bis(2-hydroxethyl)propanediamine, a long chain polydispersed β(1,4) linked mannan polymer

interspersed with O-acetylated groups, deproteined cell wall extracts from a non-pathogenic stain of Mycobacterium, mannite monooleate and paraffin oil.

Independent claim 56 is drawn to a vaccine which protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one attenuated biotype and a pharmaceutical acceptable excipient wherein the clinical disease includes respiratory pneumonia.

Boothby teaches a vaccine composition comprising killed *Mycoplasma bovis* and phosphate buffered saline used for systemic immunization of calves (page 130). Boothby also teaches vaccine preparations comprising 0.5 ml killed *Mycoplasma bovis* antigen, 1 ml of Freund's incomplete adjuvant and 0.5ml of various aqueous solutions (page 131). Boothby teaches that the vaccine preparations used contained 5.00 mg/ml of antigen for immunization (page 131) which meets the claim limitations " wherein the amount of each inactivated biotype is at least 10^8 *M. bovis* cells". Boothby teaches that *M. bovis* is not highly immunogenic in the bovine. Boothby teaches that immunopotentiating effect of adjuvants may be used to prolonged deposition of antigen, modification the antigen or the recruitment and/or activation of the circulating lymphoid or reticuloendothelial cells (page 129). Boothby teach that adjuvants have been used in successful vaccine preparations of *M. bovis* and other pathogenic mycoplasmas. Boothby further teaches that adjuvants would be of particular benefit if found for local immunization where lymphocytes and phagocytic cells are suppressed or where small amounts of antigen is preferred to avoid undesirable reactions (page 129).

Boothby does not teach the use of at least two inactivated or attenuated *M. bovis* biotypes.

Poumarat et al disclose 37 *Mycoplasma bovis* strains from 13 different genomic groups (i.e. biotypes)(see the Abstract). Poumarat et al disclose that based on the combination of the different electrophoretic profiles obtained with the three enzymes, the 37 strains could be classified in 13 genomic groups (table 2).

Boothby and Poumarat et al do not teach the use of attenuated *M. bovis* biotypes.

Thorns et al teach attenuated bovine strains of *M. bovis*. Thorns et al teach that mice were inoculated with 0.1 of E medium containing a known number of colony forming units (CFU) of *M. bovis*. Thorns et al teach that the attenuated strains (passaged more than 60 times) contained an inoculum per gland of 5.1-7.0 cells (cells measured ($\log_{10}$)((see Table 1, page 329). This amount meets the claim limitation "wherein the amount of each attenuated biotype is at least 10^5 *M. bovis* cells. Thorns et al teach that the *M. bovis* strains were passaged in liquid medium more than 60 times were markedly less virulent than the same or different strains with fewer passages. Thorns et al teach that the high passaged *M. bovis* strains were less virulent and produced only minor histopathological changes in vaccinated animals (see the Abstract). Thorns et al teach that the modified strains of *M. bovis* (high passage strains) should provide further insight into the pathogenesis of *M. bovis* mastitis which could perhaps lead to a stable vaccine for this disease (page 332).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the attenuated *M. bovis* strains of a taught by Thorns et al and the multiple *M. bovis* biotype isolates as taught by Poumarat et al and modify the vaccine composition comprising inactivated *M. bovis* and PBS to include a suitable adjuvant because Poumarat et al teach that there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis* collected from different geographic origins and that antigenic variability must be taken into account in developing diagnostic and vaccination strategies (page 319) and Thorns et al has demonstrated that high passaged *M. bovis* strains were less virulent and produced only minor histopathological changes in vaccinated animals and do not cause systematic changes in inoculated animals. Additionally, Boothby teaches that immunopotentiating effect of adjuvants may be used to prolonged deposition of antigen, modification the antigen or the recruitment and/or activation of the circulating lymphoid or reticuloendothelial cells (page 129). It would be expected that a vaccine composition comprising inactivated *M. bovis* strains of multiple biotypes, attenuated *M. bovis* strains of multiple biotypes, PBS and a suitable adjuvant would be effect against infections caused by *M. bovis.*

(10) Response to Arguments

I. Response to Arguments Traversing the Rejection of claims 1, 3, 5-6, 29-30, 40-44 and 52-55 under 35 U.S.C .102(b) as anticipated by Boothby, *(Immunologic Responses to Mycoplasma bovis, University Microfilm International (Dissertation) 1-172, 1982)*.

Appellants Specific Arguments Restated

Appellant urges that the real difference between the claimed vaccine and the vaccine of the prior art is the nature of the claimed vaccine. Applicant urges that the claimed vaccine demonstrate no undesirable side effects.

Appellant urges that Boothby does not disclose particular biotypes of *Mycoplasma bovis*.

Appellant urges that the claimed vaccine must be "protective against *Mycoplasma bovis* mastitis in a bovine species. Appellant urges that the Examiner argues intended used for the vaccine and they disagree with this assertion. Appellant urges that the vaccine of Boothby were not protective against mastitis.

Appellant refers to Heller et al, 1993, when referring to methods of controlling the spread of *Mycoplasma bovis* caused mastitis. Appellant refers to Heller's statement "to control the spread of this disease, an early detection of the pathogen is crucial since the removal and culling of infected cows is necessary to prevent fresh infection" to support their position.

Appellant urges that Hanson, September 2001, and Hanson October 2001 describe method to prevent mastitis or mitigate its effects but the methods do not include vaccination, indicating that no vaccine protective against mastitis was known in the art. Appellant urges that the Office refused to consider this evidence in the Office action dated May 25, 2005. Appellant urges that the Office action dated May 25, 2001 cited *In re Casey*, 370 F. 2d 576, 152 USPQ 235 (CCPA 1967) and In re Otto, 312 F. 2d 937, 136 USPQ 458 (CCPA 1963) in support of their position with respect to the claim limitation of protection against mastitis. Appellant urges that *Casey* is not applicable to the present fact pattern because the functional properties of the claimed device in *Casey* were found inherently disclosed in the Kienzle prior art reference. Appellant urges that the functional property of being protective against mastitis is not found in the prior art explicitly or inherently.

Appellant urges that *In re Otto*, the claims where rejected for obviousness over a large number of references that collectively disclosed all the recited claim limitations.

Appellant refers to *Union Oil Co. of Cal v. Atlantic Richfield Co.,* 208 F.3d 989, 54, U.S.P.Q. 2d 1227 (Fed. Cir. 200) to support their position. Appellant concludes that the instant specification stresses the problem of mastitis and teaches that vaccines of the present invention address that problem by providing actual data showing the vaccines protect against mastitis. Appellant draws this conclusion based on the fact pattern outlined in *Union Oil Co. of Cal v. Atlantic Richfield Co.*

Appellant urges that the claims 52 and 55 recite that the vaccines of the invention comprise an adjuvant selected from a group that does not include the adjuvants listed in Boothby. Thus, these claims are not anticipated.

Examiner's Response to Appellant's Arguments

I. Applicant's arguments filed March 7, 2008 have been fully considered but they are not persuasive.

The claims are directed to vaccine compositions comprising at least one inactivated or attenuated *Mycoplasma bovis* biotype, an adjuvant, pharmaceutically acceptable excipient and wherein the wherein the adjuvant does not include saponin and the clinical disease includes respiratory pneumonia.

Boothby teach vaccine compositions comprising at least on formalin inactivated *M. bovis* in PBS (pages 40 and 131) Boothby also teach that adjuvants such as Freund's incomplete adjuvant were used in the vaccine compositions (pages 131-132). Both the claimed vaccine and the vaccine of the prior art comprises (a) an inactivated (killed) *Mycoplasma bovis* biotype, (b) a pharmaceutically acceptable excipient (phosphate buffered saline) (PBS)) and (c) an adjuvant (for example, Freund's complete adjuvant). Therefore, the cited prior art teaches a vaccine compositions that have the same components as the claimed vaccine composition. It should be noted that the MPEP 2112.01 states that "*Products of identical chemical composition can not have mutually exclusive properties." a chemical composition and its properties are inseparable*. Therefore, if the prior art teaches the identical chemical structure, the

properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymerlatexes for lack of novelty.").

With respect to Appellant argument, "the vaccine compositions of the prior art cause adverse reactions and the claimed vaccine composition do not". Applicant is arguing limitations that are not in the claims. There is no claim limitation regarding favorable, unfavorable or any kind of reactions as they relate to the claimed vaccine compositions.

With respect to Appellant's argument regarding, Boothby not disclosing biotypes, it should be noted that *Mycoplasma bovis* can be identified as a certain biotype. See for example, Poumarat et al, 1994 (already of record). Therefore, by merely teaching *Mycoplasma bovis*, the biotype of the strain of *Mycoplasma bovis* used is inherently present.

In response to applicant's argument regarding that "the claimed vaccines are protective against *Mycoplasma bovis* mastitis", the Examiner is viewing this limitation as limitation of intended use. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it

meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Applicant has not provided a side-by-side comparison to show that the vaccines of the prior art differ from the claimed vaccine.

In response to Appellant's argument regarding Heller et al, 1993, it should be noted that Heller et al is directed to antigen capture of ELISA using a monoclonal antibody for the detection of *Mycoplasma bovis* in milk. This reference does not teach or disclose a vaccine comprising an inactivated or attenuated *M. bovis* biotype, an adjuvant and an pharmaceutically acceptable excipient. Heller merely states that the spread of mastitis can be controlled by early detection.

In response to Appellant's argument regarding Hanson, September 2001 and October 2001, it should be noted that these references point out that *Mycoplasma* mastitis is a major problem in dairy industry. These references do not teach or disclose a vaccine comprising an inactivated or attenuated *M. bovis* biotype, an adjuvant and an pharmaceutically acceptable excipient. Contrary to Appellant's statements on the record, Heller et al, 1993, Hanson, September 2001 and Hanson, October 2001 were consider for their content and as they relate to *Mycoplasma bovis* problems associated with the dairy industry. However, as stated above, these references do not teach the claimed vaccine. They give an assessment of the problems mastitis has caused in the dairy industry and outline efforts to detect *Mycoplasma bovis* in milk samples.

With respect to Appellant's arguments regarding *In re Casey*, the Examiner is viewing the claim limitations "which is protective against respiratory pneumonia" or "which is protective against *Mycoplasma bovis* mastitis" or any *Mycoplasma bovis* clinical disease as limitations of intended use. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Applicant has not established a structural difference between the claimed vaccine and the vaccines of the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA). Thus, in view of *In re Casey,* the vaccine compositions of the prior art would inherently have the same functional properties. With respect to Appellant's arguments regarding *In re Otto*, like with *In re Casey,* the vaccines of the prior art and the claimed vaccines comprise the same components, thus they would have the same functional properties.

In response to Appellant's argument regarding *Union Oil Co. of Cal v. Atlantic Richfield Co.,* Appellants may have recognized that there is a problem of mastitis in the dairy industry and teaches that vaccines of the present invention address that problem. However, the problem is that the vaccines of the claimed invention and the vaccines that are already known in the art are not structurally different. It should be

remembered that the claims are drawn to vaccines, products and not a method of using that product.

With respect to Appellant's arguments regarding claims 52 and 55 reciting a group of specific types of adjuvants, Boothby teaches vaccine compositions comprising aluminum hydroxide (page 131). Thus, Boothby anticipates these claims.

In view of all of the above, Boothby anticipates the claimed invention.

Appellants Specific Arguments Restated

II. Appellant urges that as stated above, the claimed vaccine does not cause unfavorable reactions. Appellant urges that the vaccines of Boothby causes hypersensitivity and the *M. bovis* in Thorns caused histopathological changes. Appellant urges that Poumarat et al do not disclose vaccines of any kind and failed to teach or suggest a vaccine that does not cause unfavorable reactions. Appellant urges in view of the complete lack of disclosure of the claim limitation "a vaccine that does not cause unfavorable reactions", the combination of references do not disclose or suggest this claim limitation. Appellant urges that a prima facie case of obviousness has not been made.

Appellant urges that claims 8-12, 31-39 and 46-51 recite at least two "*M. bovis* biotypes". Appellant urges that Boothby do no disclose a vaccine that contains more than one biotype. Appellant urges that Thorns et al do not disclose a vaccine with more that none biotype. Appellant urges that Poumarat et al do not disclose any vaccines since Poumarat is limited to a study of the antigenic characteristics of certain strains of *Mycoplasma bovis*. Appellant urges that Poumarat et al teach away from the use of

more than one biotype. Appellant urges that Poumarat et al divided *M. bovis* biotype isolates into 13 different "genomic groups". Appellant urges that Poumarat et al then looked at the antigenic variability between and among these genomic groups. Appellant urges that Poumarat et al found much antigenic variability, this variability did not correlate with membership in any particular genomic group. Appellant concludes that because Poumarat et al teach that antigenic variability is as great within *Mycoplasma bovis* groups as across *Mycoplasma* groups, there is no gain in antigenic variability from including more than one type of *M. bovis* in a vaccines. Appellant urges that the findings of Poumarat et al would discourage one of ordinary skill in the art from including more than one biotype in a vaccine composition.

Appellant urges that Boothby, Thorns et al or Poumarat et al do no teach or suggest the claims limitation "protective against *Mycoplasma bovis* mastitis". Appellant urges that Hanson, September 2001, and Hanson October 2001 disclose problems caused by bovine mastitis. Appellant urges that Boothby, *(Can. J. Vet, Res., 1986, 50:200-204)* shows the failures of others and teaches away from the claimed invention. Appellant urges that Boothby, 1986 teach that treated animals showed poorer milk production than the untreated animals.

Appellant urges regarding claim 56 Boothby and Poumarat et al do not disclose attenuated *M. bovis*. Thorns et al disclose attenuated strains of *M. bovis,* but does states that these strains are not vaccines but might provide further insight which could perhaps lead to the development of a vaccine. Appellant urges that the combination of these prior art references does not make claim 56 obvious.

Examiner's Response to Appellant's Arguments

II. Applicant's arguments filed March 7, 2008 have been fully considered but they are not persuasive.

It is the Examiner's position that applicant argues the references individually without clearly addressing the combination of teachings. It is the combination of all of the cited and relied upon references which make up the state of the art with respect to the claimed invention.

In response to applicant's argument that no case of prima facie obviousness has been made, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). One of skill in the art would have been motivated to combine the teachings of Poumarat et al and Thorn et al to the vaccine compositions of Boothby et al because Poumarat et al teach that there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis* collected from different geographic origins and that antigenic variability must be taken into account in developing diagnostic and vaccination strategies, and Thorns et al has demonstrated that high passaged *M. bovis* strains were less virulent and produced only minor histopathological changes in vaccinated animals and do not cause systematic changes in inoculated animals. Therefore, one of ordinary skill in the art would

reasonably conclude that a vaccine composition comprising inactivated *M. bovis* strains of multiple biotypes, attenuated *M. bovis* strains of multiple biotypes, a pharmaceutically acceptable excipient and an adjuvant would be effect against infections caused by *M. bovis*.

To address Appellant's arguments regarding that the prior art references do not teach vaccine compositions that do not cause unfavorable reaction, it is the Examiner's position that Applicant is arguing limitations that are not in the claims. There is no claim limitation regarding favorable, unfavorable or any kind of reactions as they relate to the claimed vaccine compositions.

With regard to Appellant's comment regarding Poumarat et al teaching away from the claimed invention, the Examiner disagrees with this assertion. Poumarat et al has demonstrated that there is great variability among and between genomic groups of *Mycoplasma* strains. Poumarat et al teach that there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis* collected from different geographic origins and that antigenic variability must be taken into account in developing diagnostic and vaccination strategies. Pourmarat et al do not teach away from the development of vaccines using multiple biotypes, in fact it embraces the concept.

To address Appellant's comments that the prior art references do not teach "vaccine compositions that are protective against mastitis", it is the Examiner's position that the claim limitation " the vaccine compositions are protective against *Mycoplasma bovis* clinical disease" is being viewed as a limitation of intended use. It should be remembered that a recitation of the intended use of the claimed invention must result in

a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). The Examiner's comments regarding *In re Casey* and *In re Otto* can be found above.

In response to Appellant's argument regarding Hanson, September 2001 and October 2001, it should be noted that these references point out that *Mycoplasma* mastitis is a major problem in dairy industry. These references do not teach or disclose a vaccine comprising an inactivated or attenuated *M. bovis* biotype, an adjuvant and an pharmaceutically acceptable excipient.

With respect to Boothby, 1986, it should be noted that this study includes vaccinated cows without challenge and vaccinated cow with challenge, it should be noted that by the end of the study, no *M. bovis* could be recovered from challenged quarters on vaccinated cows and the milk production appeared mostly normal (Boothby1986, Abstract). This is a positive assessment for the vaccinated cows. Thus, it cannot be concluded from these results that the vaccine did not work. In fact, it appears to prove the opposite.

With respect to claim 56, as stated above, it is the combination of Boothby, Poumarat et al and Thorns et al that teach the claimed invention. Thorns et al has demonstrated that high passaged *M. bovis* strains (attenuated strains) were less virulent

and produced only minor histopathological changes in vaccinated animals and do not cause systematic changes in inoculated animals.

There is nothing on the record to show that the combination of reference does not suggest the claimed invention.

In view of all of the above, the combination of reference establishes a case of prima facie obviousness, absent convincing evidence to the contrary.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Examiner's Answer Conclusion

For the above reasons, it is believed that the Examiner should be affirmed.

Respectfully submitted,

/Vanessa L. Ford/

Examiner, Art Unit 1645

March 13, 2009

Supervisory Patent Examiner, Art Unit 1645
Conferee

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648
Conferee

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004